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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/806,721	07/11/2001	Bruce Acres	017753-132	7786

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BURNS DOANE SWECKER & MATHIS L L P
POST OFFICE BOX 1404
ALEXANDRIA, VA 22313-1404

EXAMINER	
LI, QIAN JANICE	
ART UNIT	**PAPER NUMBER**
1632	

DATE MAILED: 02/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No.	Applicant(s)	
	09/806,721	ACRES ET AL.	
	Examiner	Art Unit	
	Q. Janice Li	1632	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 12 December 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☒ The period for reply expires *4* months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☒ The proposed amendment(s) will not be entered because:

   (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);

   (b) ☐ they raise the issue of new matter (see Note below);

   (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

   (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: *See Continuation Sheet*.

3. ☐ Applicant's reply has overcome the following rejection(s): _____.

4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☒ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *See Continuation Sheet*.

6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☒ For purposes of Appeal, the proposed amendment(s) a)☒ will not be entered or b)☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:

   Claim(s) allowed: _____.

   Claim(s) objected to: _____.

   Claim(s) rejected: *1-10,21,26 and 30*.

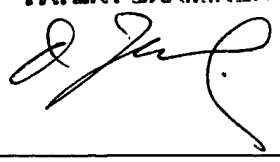
   Claim(s) withdrawn from consideration: _____.

8. ☐ The drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9. ☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____

10. ☐ Other: _____

JANICE LI
PATENT EXAMINER



Continuation of 2. NOTE: The proposed amendment adds new limitation into claims which would require further search and consideration..

Continuation of 5. does NOT place the application in condition for allowance because: With respect to the request for withdrawal of the finality of the Offical action, Applicants cited MPEP indicating that any claim ameded to include limitations which should reasonaly have been exprected to be claimed should not be made final. In response, the elected group of invention for examination in the first action includes claims 1-10, 18, 21, and 26 and is drawn to any therapeutic gene that encodes all or part of an antibody which will be expressed at the surface of any target cell, and none of the independent or dependent claims in the group is specifically drawn to a T cell receptor complex. Since the claims encompass a genus of numerous therapeutic molecules, and only generic claims are presented, the Examiner is not allowed to require species election (MPEP 809.02d), and should not be required to seach for every molecule that is encompassed by the genus, and could not have been reasonably expected which species of the genus the applicants are intend to claim. Accordingly, it is proper to make the action final when new limitations drawn to a particular subgenus of molecules on a specific target cell type is added to the claims, thus, the finality of the Official action remains.

For the same reason set forth above, the proposed after final amendment adds a new limitation drawn to a specific species of the genus of cells that would require further search and consideration, thus, the amendment will not be entered at this stage of prosecusion.

Claims 1-3, and 30 stand rejected under 35 U.S.C. 102(e) as being anticipated by Wittrup et al (US 6,423,538).
Applicants argue that Wittrup et al expressing the antibody in yeast cells, and a yeast cell is not considered as the target cell. In response, the specification does not specifically define the target cell to exclude a non-mammalian cell. The arguments drawn to amended claims are moot because the amendment has not been entered.

Claims 1-3, and 30 stand rejected under 35 U.S.C. 102(a) & (e) as being anticipated by Burkly et al (US 5,871,732), and evidenced by Janeway, Jr. et al (Immunobiology, 1999).
Applicants argue that it is not apparent that the Janeway publication disclosed that CD4 comprises TCR-alpha and TCR-beta, and submitted Cruse et al reference teaching that CD4 is a single chain glycoprotein. In response, the caption of the cited Janeway reference recites "the development of mature LYMPHOCYTE RECEPTOR repertoires", and figures show CD4+ and CD8+ T lymphocytes, which are T lymphocyte receptor (TCR) complex. Rows 4 & 5 of the table clearly illustrate that CD4 is part of the T-cell receptor complex, the figure legend further discusses the development of alpha- and beta chains on T-cell surface. Thus, the teaching meets claim limitation. The teaching of Cruse et al does not conflict with Janeway reference, because the alpha and beta chains are made of glycoproteins.

Claims 1-6, 21, 26, and 30 stand rejected under 35 U.S.C. 102(e) as being anticipated by German et al (US 6,531,455).
Applicants argue that German et al disclose methods for delivering a polypeptide to the bloodstream, whereas the presently claimed invention allows the expression of an antibody at the surface of the target cell. In response, it is noted that the use of a product for a particular purpose is not afforded patentable weight in a product claim where the body of the claim does not depend on the preamble for completeness but, instead, the structural limitations are able to stand-alone. In the instant case, since the structure of biological material taught by German et al meets claim limitation, the rejection stands.

Claims 1-10, 21, 26, and 30 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Dixit et al (US 6,562,797), in view of Schneck et al (US 6,448,071) and Wittrup et al (US 6,423,538).
Applicants argue that Dixit et al teach expressing a molecule inside the target cell, not at the target cell, Wittrup et al teach expressing the antibody at the surface of yeast cell, not a mammalian cell, and the goal of Schneck et al is to produce a soluble form of a polypeptide deriving from heterodimeric double transmembrane protein such as TCR or MHC, the antibody binding site of the antibody as depicted in figures 1c and 1d is not functional. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See In re Keller, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); In re Merck & Co., 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In the instant case, Dixit et al is relied upon for the teaching of using an antibody targeting T cell surface receptor, Wittrup et al is relied upon for constructing nucleic acid vector expressing an anti-TCR antibody, and Schneck et al is relied upon illustrating the need for studying selective interaction of T cell receptors with their cognate ligands, and a showing that it is known in the art for expressing a light chain or a heavy chain of the antibody and fused with a transmembrane polypeptide, and accordingly, the rejection stands..